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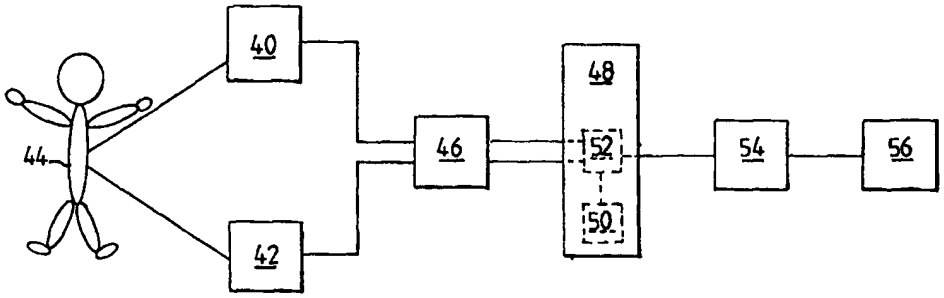


(57) Abstract

An ischemia detector comprises patient workload sensing means (40) and patient breathing sensing means (42) disposed to deliver to detecting means (48) signals representing the workload and the breathing activity respectively of the patient (44). The detecting means are arranged to detect as a state of ischemia the occurrence of a predetermined relation between sensed workload and sensed breathing activity.

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# Ischemia detector

## Technical field

The present invention relates to an ischemia detector and to an implantable heart stimulator having such an ischemia detector.

## Background Art

The blood flow and penetration in the circulatory system of a living subject is dependent on the arterial muscular tension, the so called tonus. Thus the blood flow is controlled by the tonus, the driving force of the flow is the blood-pressure in the elastic aorta and the pressure in the aorta is maintained by the pumping action of the heart. For this pumping action the heart needs energy in the form of oxygen and glucose. About 60% of the oxygen in the heart interstitial fluid is consumed within one heart beat. If the energy supplied to the heart is disturbed the heart contractibility and the pumping action of the heart are severely deteriorated and an oxygen shortage or ischemic situation will rapidly develop.

Ischemia results from insufficient blood flow through the heart muscle. The reason therefore is blocking or passage congestion of coronary blood vessels of the heart. An ischemia is experienced by the patient as a severe chest pain and is one of the most stressing factors known to the organism.

Several techniques for detecting ischemia are previously known. Thus in US-A-4,821,735 a method and an apparatus for detecting myocardial ischemia are described, wherein the systemic vascular resistance (SVR) in a subject is monitored and the presence of myocardial ischemia is detected when the SVR increases by at least 60% over a base line value.

In US-A-5,497,780 an apparatus is described for determining an ischemia by measurements of electric

potentials between at least three implanted measuring electrodes, two of said electrodes being implanted with their poles in the heart and the third electrode being implanted with its pole lying outside the heart.

In US-A-5,199,428 a technique is described for detecting ischemia and effecting stimulation of nerves regulating blood pressure and heart rate to reduce the heart's oxygen requirements while providing pacing therapies to maintain the patient's heart rate within acceptable limits to avoid bradyarrhythmias and/or unphysiological AV delays induced by the nerve stimulation. The ischemia detection is based on the occurrence of changes in the ST-segment variation different from predetermined or programmed threshold levels, or on changes in the pH and/or in the dissolved blood oxygen in venous return blood in the coronary sinus region of the patient's heart.

An ischemic state can also be detected by analysis of recorded IECG's or surface ECG's to determine the heart rate variability. An ischemia can be detected by a lead bend sensor located at the distal end portion of an implanted heart stimulator lead. As the heart wall is thickening and stiffening as the result of an ischemia, the accompanying change in the moving pattern of the heart wall can be detected in this way. Also sound absorption is affected by changes in the stiffness of the heart tissue and by measuring the absorption of sound waves, generated e.g. at the heart valve closure, on their way from the upper portion of the ventricle to the apex region, an ischemic situation can be detected. An ischemia is deteriorating the efficiency of the heart´s pumping and an ischemic situation can therefore be detected by studying blood pressures and cardiac outputs, too. Thus, by measuring the difference between the systolic and diastolic pressures and comparing this difference obtained from one heartbeat to the difference obtained from the next heartbeat an ischemia can be

detected. With the aid of a flow sensor for measuring cardiac output an ischemic state can be detected, too.

As mentioned above an ischemic state is normally associated with severe pain forcing the patient to sit down or lie down with a reduced heart rate as a consequence. At the same time the patient feels a need for forced breathing, so called hyperventilation.

Disclosure of the invention

The purpose of the present invention is to provide a new type of ischemia detector the function of which is based on the above mentioned needs of a patient affected by an ischemia.

This purpose is obtained with a detector according to claim 1.

For a healthy person the need of an increased respiration rate normally results from an increased effort or workload of the person. The ischemia detector according to the invention is based on the occurrence of the abnormal combination of low workload and high breathing activity, which is typical of ischemic patients.

According to an advantageous embodiment of the ischemia detector according to the invention averaging means are connected to said workload and breathing sensing means to form average values during time periods of predetermined lengths of workload and breathing activity respectively, and deliver corresponding average signals to said detecting means. In this way false detections due to accidental variations of transitory nature in the workload and breathing activity are avoided.

According to another advantageous embodiment of the detector according to the invention alerting means are disposed to be activated in response to a detected ischemia.

According to another aspect of the invention an implantable heart stimulator is provided having means for varying the stimulation rate and an ischemia detector as defined above.

According to an advantageous embodiment of the invention in this aspect, the heart stimulator comprises control means connected to the ischemia detector for controlling the stimulation rate varying means to lower the stimulation rate in response to the detection of an ischemia.

Brief description of the drawings

To explain the invention more in detail embodiments of the invention, chosen as examples, will be described below with reference to the drawings, on which

figure 1 is a block diagram of an embodiment of an ischemia detector according to the invention,

figure 2 is a block diagram illustrating one specific realisation of the operation of the detector according to the invention,

figure 3 is a simplified block diagram of one embodiment of the heart stimulator according to the invention, and

figure 4 shows a pacemaker with its lead implanted in the right ventricle of the heart.

Description of preferred embodiments

Figure 1 illustrates a workload sensor 40 and a breathing activity sensor 42 disposed for sensing the workload and the breathing activity respectively of a patient 44 and delivering corresponding signals to an averaging means 46, in which average values during time periods of a predetermined length are formed of the workload and breathing activity signals. These average signal values are supplied to detecting means 48.

The detecting means 48 comprises a memory 50, in which one or more relations between workload and breathing activity are stored, and comparing means 52, in which the relation obtained between the signals from the averaging means 46 representing workload and breathing activity is compared to the predetermined relations stored in the memory 50.

When a predetermined relation between the signals from the averaging means 46 is detected alerting means 54 connected to the comparing means is triggered to indicate the occurrence of ischemia. A heart stimulator 56 is connected to the alerting means 54 for lowering the stimulation rate in response to the detection of an ischemia, as will be described more in detail below.

An example of the predetermined relation between workload x and breathing activity y stored in the memory 50 is a linear relationship like

$$ax + by = c$$

where a, b, and c are constants. However, different kinds of non-linear relations are common too.

An alternative embodiment of the detecting means is shown in figure 2. In this embodiment the detecting means 58 comprises two comparators 60, 62 to which the workload signal and the breathing activity signal respectively are supplied for comparing the signals with predetermined threshold values Ref 1 and Ref 2. The outputs of the comparators 60, 62 are connected to the inputs of an AND-gate 64.

The comparator 60 is arranged to deliver an output signal when the workload signal is below the predetermined workload threshold value Ref 1 and comparator 62 delivers an output signal if the breathing activity signal is above the predetermined breathing activity threshold value Ref 2 and in this case an output signal is obtained from the AND-gate 64 for e.g. activation of ischemia alerting means.

Figure 3 is a simplified block diagram of an implantable heart stimulator 2 according to the invention. The heart stimulator 2 comprises an ischemia detector comprising ischemia detecting means 4, and control means 6, connected to the ischemia detecting means 4. The control means 6 are connected to a pulse generator 8 for controlling the rate of generated stimulation pulses. The pulse generator in its turn is connected to a lead 10 provided with electrodes 12 at the distal end portion for

delivery of stimulation pulses and for possible electrical measurements, which lead 10 is intended to be implanted into the heart of a patient, preferably with the electrodes in the right ventricle, cf. figure 4. Sensing means 14 are also provided at the distal end portion of the lead 10 and sensed signals are supplied to the ischemia detecting means 4 through the lead 10.

Workload sensing means 11 in the form of e.g. an accelerometer for sensing body movements of the patient or a sensor for sensing muscular sounds of the patient are also provided in the heart stimulator 2. For detecting muscular sounds the stimulator case can be used as a microphone and the associated electronics for recording the oscillations of the wall of the case can be glued onto the inner side of the case wall.

The sensing means 14 can be used for recording IECG's and comprise electrodes as described in connection with figure 4. The signals are supplied by the lead 10 to an IECG recording unit 5. The IECG recording unit 5 comprises a sensor for sensing the IECG baseline offset and determining the breathing activity from this baseline offset. The baseline offset is preferably measured on a small DC bias voltage. An output signal from the IECG recording unit 5 is delivered to the ischemia detecting means 4.

The DC bias voltage is supplied during a fraction of the breathing cycle and at certain defined positions of the cardiac cycle.

The heart stimulator 2 is also provided with alerting means 13, e.g. of a wrist watches "beeper-type".

These alerting means 13 are connected to the ischemia detecting means 4 to be activated by a detected ischemia. Alternatively the alerting means can be connected to the control means 6 to be activated when the stimulation rate is lowered. This is of value for patients having a "silent" ischemia, the occurrence of which the patient would otherwise not be aware of.

Figure 4 shows an implanted heart stimulator in the form of a pacemaker 16, connected to the right ventricle 18 on the heart of a patient by its lead 20, which is of a bipolar type with an electrode ring 22 and with a tip electrode 24 and sensing means 26, 28.

With the heart stimulator according to the invention the stimulation rate is reduced in response to the detection of an ischemia. There are different possibilities of reducing the stimulation rate. The control means 6 can inhibit the delivery of a particular stimulation pulse thus temporarily producing a longer interval between two consecutive pulses. The control means 6 can also be arranged to more regularly inhibit a stimulation pulse out of a specified number of stimulation pulses in response to a detected ischemia. The control means 6 can also be arranged to control the pulse generator such that the stimulation rate is uniformly reduced on the detection of an ischemia, or the stimulation rate can be shifted to selected lower rates.

The breathing activity can be determined by measuring the AC impedance between the two electrodes 22, 24 of the electrode lead 20 or between one of the electrodes 22, 24 and the case of the pacemaker 16.

The electrodes 22, 24 or the sensing means 26, 28 can be used for measuring amplitude modulation of sensed cardiac activity for determining the breathing activity from this measured modulation.

Other possibilities of determining the breathing activity of the patient is by using a sensor for sensing breathing sounds in the thorax of the patient or a sensor for sensing lung volume changes.

Also other kinds of workload sensing means can be used in the present invention. Thus the workload sensing means can comprise a sensor for sensing pressure waves in body fluids generated by the workload or activity of the patient. The workload sensing means can comprise a sensor for sensing metabolic changes, like changes in nutrition and oxygen consumption of the patient.

Claims

1. An ischemia detector, **characterized by** patient workload sensing means (11;40) and patient breathing sensing means (14;26,28;42) disposed to deliver to detecting means (4,48,58) signals representing the workload of the patient (44) and the breathing activity of the patient respectively, said detecting means being arranged to detect as a state of ischemia the occurrence of a predetermined relation between sensed workload and sensed breathing activity.

2. The ischemia detector according to claim 1, **characterized in** that said predetermined relation is a linear relation between sensed workload and sensed breathing activity.

3. The ischemia detector according to claim 1, **characterized in** that said detecting means (4,48,58) are arranged to detect as a state of ischemia a sensed low workload and a simultaneously sensed high breathing activity.

4. The ischemia detector according to claims 1 or 3, **characterized in** that said detecting means (58) are arranged to detect as a state of ischemia a sensed workload, which is below a predetermined workload threshold value (Ref 1), and a simultaneously sensed breathing activity, which is above a predetermined breathing threshold value (Ref 2).

5. The ischemia detector according to any of the claims 1 through 4, **characterized in** that averaging means (46) are connected to said workload and breathing sensing means (40,42)to form average values during time periods of

predetermined lengths of the workload and the breathing activity respectively and deliver corresponding average signals to said detecting means (48).

6. The ischemia detector according to any of the claims 1 through 5, **characterized in** that said workload sensing means (11,40) comprise an activity sensor for sensing body movements of the patient.

7. The ischemia detector according to any of the claims 1 through 5, **characterized in** that said workload sensing means comprise a sensor (16) for sensing muscular sounds of the patient.

8. The ischemia detector according to any of the claims 1 through 5, **characterized in** that said workload sensing means (11,40) comprise a sensor for sensing pressure waves in body fluids due to the workload of the patient.

9. The ischemia detector according to any of the claims 1 through 5, **characterized in** that said workload sensing means (11,40) comprise a sensor for sensing metabolic changes, like changes in nutrition and oxygen consumption, of the patient.

10. The ischemia detector according to any of the claims 1 through 9, **characterized in** that said patient breathing sensing means comprise a sensor (42) for sensing breathing sounds in thorax of the patient.

11. The ischemia detector according to any of the claims 1 through 9, **characterized in** that said patient

breathing sensing means comprise a sensor (42) for sensing lung volume changes.

12. The ischemia detector according to any of the claims 1 through 9, **characterized in** that said patient breathing sensing means comprise a sensor (14;26,28;42) for measuring amplitude modulation of sensed cardiac activity and for determining the breathing activity from the measured modulation.

13. The ischemia detector according to any of the claims 1 through 9, a device for recording IEGM being provided, **characterized in** that said patient breathing sensing means comprise a sensor (5,14;22,24;26,28) for sensing the IEGM baseline offset and determining the breathing activity from the measured baseline offset.

14. The ischemia detector according to claim 13, **characterized in** that said sensor (5,14) for measuring the IEGM baseline offset is arranged to measure the baseline offset on a small DC bias voltage.

15. The ischemia detector according to claim 14, **characterized in** that means are provided to apply the DC bias voltage during a fraction of the breathing cycle and at certain defined positions of the cardiac cycle.

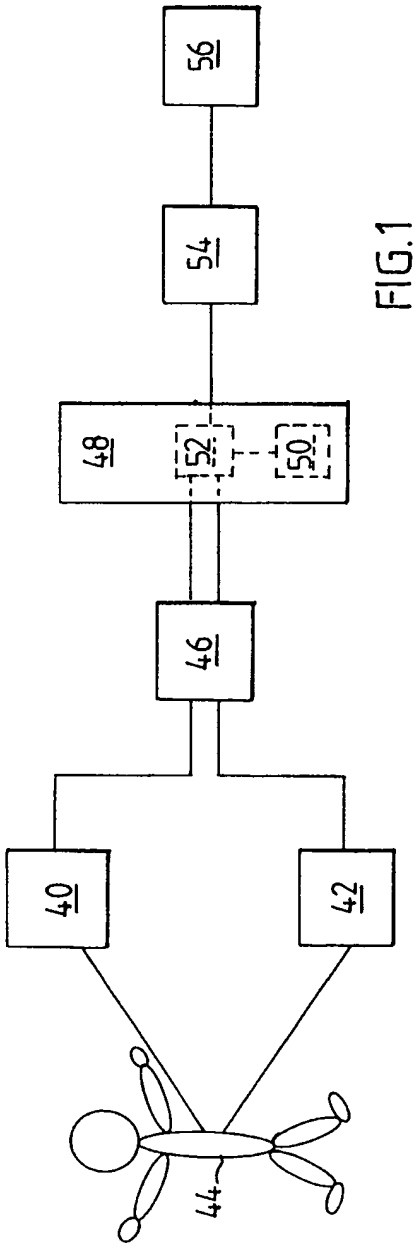
16. The ischemia detector according to any of the claims 1 through 15, **characterized by** alerting means (13,54), disposed to be activated in response to a detected ischemia.

17. The ischemia detector according to any of the claims 1 through 9, said ischemia detector being comprised

in an implantable heart stimulator (2,16), **characterized in** that said patient breathing sensing means comprise a sensor (14) for measuring the AC impedance between two electrodes (22,24;26,28) of an electrode lead (20) of the stimulator or between one electrode of the lead and the case of the stimulator (16) for determining the breathing activity from the measured AC impedance.

18. Implantable heart stimulator, having means (8) for varying the stimulation rate, **characterized by** an ischemia detector according to any of the claims 1 through 17.

19. The heart stimulator according to claim 18, **characterized in** that control means (6) are connected to the ischemia detector for controlling the stimulation rate varying means (8) to lower the stimulation rate in response to the detection of an ischemia.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44

FIG.1

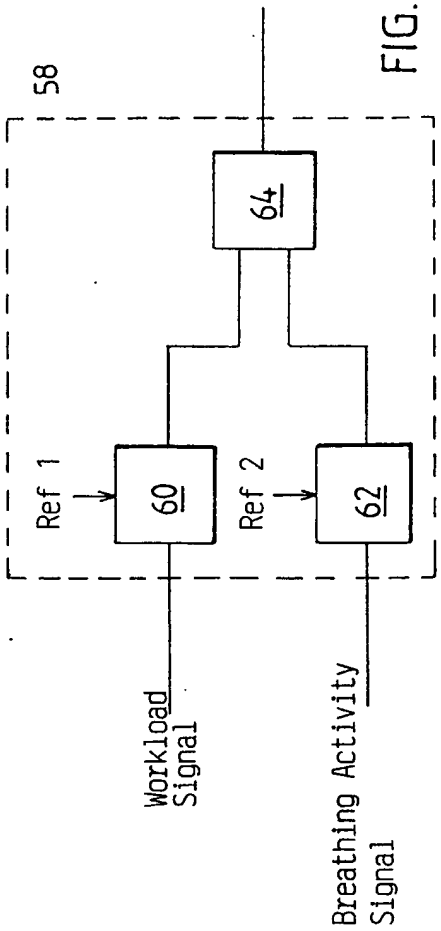
58
64
Ref 1
60
Ref 2
62
Workload Signal
Breathing Activity Signal

FIG. 2

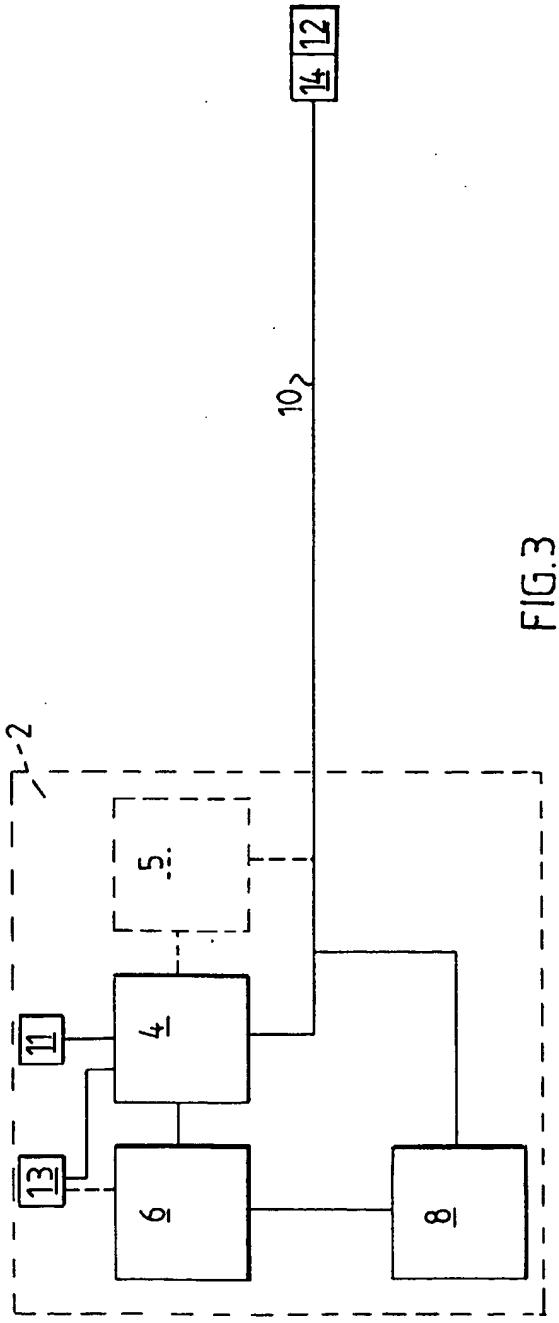


FIG.3

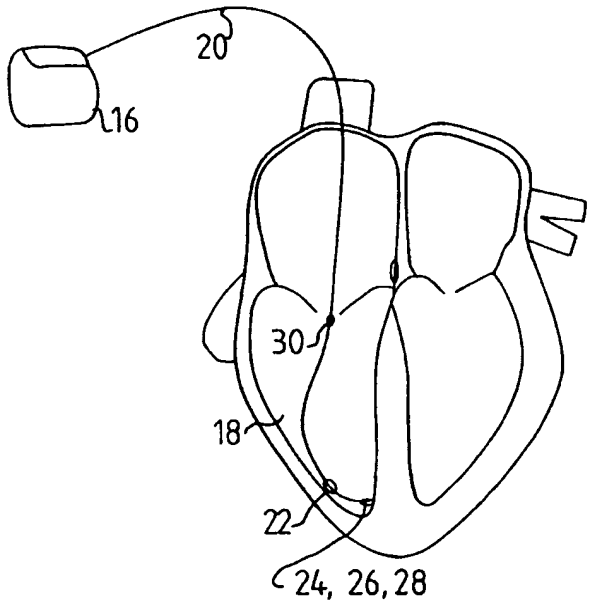


FIG. 4

# INTERNATIONAL SEARCH REPORT

International application No.
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A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61B 5/0205, A61N 1/365
According to International Patent Classification (IPC) or to both national classification and IPC

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

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| A | US 5025786 A (S.B. SIEGEL), 25 June 1991 (25.06.91), see the whole document<br>---<br>-------- | 1-19 |

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